REMARKS

Summary of Office Action

Claims 1, 3, 9-10, 13-15, 18, 22, 25, 28-29, 36-37, 39 and 45-46 are pending in this application. Claims 1, 14, 18 and 37 were rejected under 35 U.S.C. 102(b) as being anticipated by Henley, U.S. Patent No. 5,415,629 ("Henley"). Claims 1, 3, 9-10, 13-15, 18, 22, 25, 28-29, 36-37, 39, and 45-46 were rejected under 35 U.S.C. 103(a) as being unpatentable over Burson et al. U.S. Patent No. 6,615,078 ("Burson") in view of Henley, and in further view of Neubauer et al. U.S. Patent No. 5,255,692 ("Neubauer").

Summary of Applicants' Reply

Applicants have amended claims 18 and 37. No new matter has been added. Applicants respectfully traverse the rejections.

Applicants' Reply to the Prior Art Rejections

I. Henley Fails to Teach or Suggest a Retainer

Independent claims 1, 18, and 37 relate to an electrode for an iontophoretic drug delivery system including, *inter alia*, a platform, a retainer operably connected to the platform, a conductor connected to the platform, and a drug delivery matrix being operably connected to the platform and proximate the conductor. The platform, for example, is a base or a substrate to which other elements of the electrode are secured (see applicants' Original Specification, pg. 4, paragraph 22; Fig. 1). The retainer is connected to the platform and includes a malleable characteristic. The malleable characteristic enables the retainer to be shaped into a desired configuration and retained, for example, by use of structural memory material (see applicants' Original Specification, pg. 5, paragraphs 18 and 24). The malleable aspect of the retainer also allows the electrode to be bent, molded and retained into a specific shape to conform, for example, to a variety of body contours (see applicants' Original Specification, pg. 4, paragraph 18). An exemplary retainer that has a malleable characteristic is shown as element 16 in Figure 1 of applicants' originally-filed application and discussed at paragraphs 18-25. Independent claim 29 recites a similar feature.

Henley does not teach or suggest a retainer operably connected to a platform and having a malleable characteristic. Henley discloses a iontophoretic applicator electrode with mounted piezoelectric elements (Henley, abstract; Fig. 1). The device includes a flexible conductive matrix **15**, a medicament carrying layer **18**, a multi-channel electrode **14**, piezoelectric crystal elements **11**, and photoetched connections **12** for driving the piezoelectric elements (Henley, col. 7, line 53 – col .8, line 3; Fig. 1). Henley fails to teach or suggest a retainer connected to a platform and having a malleable characteristic. In fact, Henley make no mention at all of a malleable material or component, let alone using such material or component as a retainer, as recited in applicants' claims. Accordingly, applicants respectfully request reconsideration and withdrawal of the 35 U.S.C. 102 rejection of claims 1, 14, 18, and 37.

II. Burson, Henley and Neubauer, Taken Alone or in Combination, Fail to Teach or Suggest a Retainer

Burson discloses an autosensor for use in an iontophoretic sampling system (Burson, col. 18, lines 25-27; Fig. 1). The autosensor includes a patient liner **130**, a collection reservoir assembly **120**, and a biosensor electrode assembly **104** and **106** (Burson, col. 18, lines 27-41). While Burson discloses that the collection reservoir assembly includes a "gel retaining layer" **126**, Burson does not teach or suggest that this "gel retaining layer," or any other layer, includes a malleable characteristic which allows it to retain a desired shape. Instead, Burson teaches that the "gel retaining layer" merely acts to "retain" two hydrogel inserts **122** and **124** (see Burson, col. 18, lines 34-37). Thus, Burson fails to teach or suggest a retainer having a malleable characteristic.

Additionally, contrary to the Examiner's assertions, Burson fails to teach or suggest a dose controller and a drug delivery means. Burson states that its biosensor functions by detecting the presence of a target analyte, and extracting substances through the skin through the process of reverse iontophoresis (Burson, col. 20, lines 8-16). Thus, not only does Burson not teach a dose controller or a drug delivery means, but also Burson would have no use for either component because the process of detecting and extracting substances through the skin (reverse iontophoresis) is opposite that of delivering drug doses through the skin (iontophoresis).

Neubauer discloses an electrode for implantation in a patient. The electrode is a sheet **20** formed from titanium or platinum and has a shape and size conforming to an interspace between the periost and the bone at the inner side of a rid proximal to the heart of a patient (Neubauer, abstract; Col. 3, lines 43-45). Neubauer discloses that the electrode sheet **20** can be made of shape-memory metal to facilitate implantation of the electrode by the surgeon (Neubauer, col. 5, lines 43-50). However, not only does Neubauer fail to teach or suggest a malleable retainer being operably connected to a platform, Neubauer fails to teach or suggest a platform at all.

As discussed above, Henley also fails to teach or suggest a malleable retainer as recited in applicants' claims. Therefore, Burson, Henley and Neubauer, whether taken alone or in combination, fail to teach or suggest each and every element of Applicants' independent claims 1, 18, 29 and 37, or of claims 3, 9-10, 13-15, 22, 25, 28, 36, and 45-46 which are dependent on claim 1, 18, 29 and 37. Accordingly, applicants respectfully request reconsideration and withdrawal of the 35 U.S.C. 103 rejection of claims 1, 3, 9-10, 13-15, 18, 22, 25, 28-29, 36-37, 39, and 45-46.

Conclusion

Applicants assert that claims 1, 3, 9-10, 13-15, 18, 22, 25, 28-29, 36-37, 39 and 45-46 are allowable, at least for the reasons set forth above in addition to other distinctive features recited therein, and respectively request that the Examiner withdraw the rejections.

In view of the above, Applicants believe the pending application is in condition for allowance.

Applicants believe no fee is due with this response other than as reflected on the enclosed Transmittal. However, if a fee is due, please charge our Deposit Account No. 18-1945, from which the Undersigned is authorized to draw.

Respectfully submitted,

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